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Hewlett-Packard StressWriter Modification 510(k) Notification

3/8/96

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Attachment I: 510(k) Summary of Safety and Effectiveness

General Information

Device Generic Name: Stress Exercise Testing System

Device Trade Name: M2488A StressWriter Exercise Testing System

Legally marketed predicate device: M2488A StressWriter Exercise Testing System

Applicant:

Hewlett-Packard
Diagnostic Cardiology Division
1700 South Baker Street
McMinnville, Oregon 97128

Indications for Use:

The intended use of the M2488A HP StressWriter Exercise Testing System is to produce accurate measurements of the heart's response to exertion.

Exercise electrocardiography is a commonly used non-invasive technique used to help detect coronary artery disease. This type of diagnostic tool can assist a physician in two important ways:

- Report ECG changes which may indicate whether coronary circulation is able to increase the oxygen supply to muscle tissue in response to increased demand.
- Assess the patient's overall exercise capacity.

Typical applications of exercise electrocardiography could include the following:

- Evaluating patients with symptoms suggestive of coronary disease
- Determining the prognosis and severity of coronary disease
- Evaluating the effects of medical and surgical therapy
- Screening for latent coronary disease
- Evaluating patients with stable congestive heart failure
- Evaluating patients with arrhythmias
- Evaluating the patient's functional capacity, and developing exercise prescriptions
- Evaluating patients with congenital heart disease
- Evaluating patients with exertional shortness of breath, dizziness, or syncope

- Evaluating cardiac rehabilitation
- Evaluating patients with rate-responsive pacemakers
- Evaluating sports medicine patients

Physicians typically evaluate the electrocardiogram for ST segment depression or elevation and or QRS alterations. This information is used by a physician in conjunction with other clinical information to diagnose and provide treatment.

Device Description:

The M2488A HP StressWriter Exercise Testing System is a basic, easy-to-use diagnostic system which provides the physician with exercise ECG test performance capability. The system is principally a stress ECG software application running on a personal computer which uses a cardiograph for signal acquisition and printing. The system provides an interface with an exercise device, either a treadmill or bicycle ergometer.

The system consists of a PageWriter cardiograph (models M1700A or M1770A or M1771A or M1772A), a high performance personal computer including a high resolution Ultra VGA display, and an isolation transformer. Exercise devices and cart are not part of the M2488A system and must be purchased separately.

The system provides measurements of the ST level and slope during a stress test. The automatic execution of the routine stress test activities allow the physician to pay more direct attention to the patient and the patient's condition. The system incorporates algorithms and a filtering system to discriminate between useful ECG signals and artifacts. The filtering system helps ensure an effective stability of the ECG signal.

System features:

- SuperTrace baseline wander filter
- ST segment measurements in all 12 leads
- Data acquisition from 12 simultaneous leads
- Digital patient module minimizes cable noise
- Periodic 12 lead reports in various formats
- Rhythm strips in 3 or 6 channel format
- Various summary reports plus signature-ready final report
- High resolution screen displays:
 - Patient name
 - Heart rate
 - Blood pressure
 - Phase and stage time
 - Treadmill speed and grade
 - Ergometer workload
 - Reference averaged complexes

- Current averaged complexes
- ST level and slope
- Protocol selected
- 3 channels of ECG rhythm
- Variety of exercise protocols
- Conforms to applicable IEC, UL, and AAMI standards

The M1700A PageWriter XLI cardiograph and the M177XA series cardiographs are currently marketed (K#895520 and K#935772 respectively). The cardiographs have been modified for use in this application by the addition of communication circuitry. The cardiograph software has been revised to accommodate communication with the personal computer. The hardware and software modifications to the cardiographs do not interfere in any way with the intended use of the cardiograph as previously cleared for market.

Marketing History

The M2488A StressWriter Exercise Testing system is not currently sold in the US. or foreign markets.

Adverse Effects of the Device on Health

All exercise ECG testing has an inherent risk due to the stress placed on the patient during the test. Beyond the inherent risk of a stress test procedure is risk associated with the proper function and control of the exercise device. If the exercise device control failed the exercise device could injure the patient. The level of concern associated with exercise device control software module has been determined to be moderate.

The level of concern is minor regarding direct risks to the patient as a result of the stress ECG measurement software. In many years of experience, there has been no reported instance of a patient suffering acute adverse effects, much less death, irreversible illness or permanent injury, as a consequence of the use of the stress ECG measurement software. There is no known case of stress ECG management software failure which would result in direct injury or death to the patient.

Clearly, the risk of not using the system is the lack of diagnostic information which may affect the physician's assessment of the patient and treatment decisions.